UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/900,147	07/09/2001	Nicholas B. La Thangue	620-149	4292

23117 7590 07/14/2005

NIXON & VANDERHYE, PC
901 NORTH GLEBE ROAD, 11TH FLOOR
ARLINGTON, VA 22203

EXAMINER	
YU, MISOOK	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 07/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/900,147	LA THANGUE ET AL.	
	Examiner	Art Unit	
	MISOOK YU, Ph.D	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 April 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-37* is/are pending in the application.

4a) Of the above claim(s) *33-35 and 37* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-25,27,28,30-32 and 36* is/are rejected.

7)☒ Claim(s) *26 and 29* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. 09308935.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Claims 33-35 and 37 drawn to method remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) for reasons in the Office action mailed on 6/18/2003.

Claims 21-37 are pending and claims 21-32, and 36 are under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

This Office action contains new grounds of rejections and objections.

Claim Rejections - 35 USC § 112, Withdrawn

The rejection of claim 29 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the amendment.

Claim Rejections - 35 USC § 101, Withdrawn

The rejection of claims 21-32, and 36 under 35 USC 101 because the claimed invention is directed to non-statutory subject matter is withdrawn in view of the amendment.

Claim Rejections - 35 USC § 102, Maintained

Claims 22-24, 27, and 30-32 remain rejected, claim **36 is newly rejected** under 35 U.S.C. 102(e) as being anticipated by US Pat 5,863,757 (filing date of May 11, 1995).

Claims are interpreted as drawn to a fragment of SEQ ID NO:1 (claims 22-24). Claim 27 is interpreted as drawn to a polypeptide comprising SEQ ID NOs 2-7 as the first portion, wherein said polypeptide further comprises a sequence of amino acids not naturally contiguous to the first portion in DP-1. Claims 30-32, and 36 are broadly interpreted as drawn to composition comprising a polypeptide comprising SEQ ID NO:1 or fragment thereof and pharmaceutically acceptable carrier (claims 30, 32) or a cytostatic or cytotoxic agent (claim 31, and 36).

Applicant argues that SED NO: 13 fails to teach or suggest a polypeptide of the presently claimed invention.

This argument has been considered fully but unpersuasive. As stated in the previous Office action, SEQ ID NO: 13 (listed in column 37 and 38) of US Pat 5,863,757 is a fragment of SEQ ID NO:1 (i.e. amino acid residue #5 to 21), thus anticipating the "the first fragment of a sequence" in claim 22, and those specific sequences in claims 23, and 24. The GST tag is a sequence not naturally contiguous to the first portion in DP-1, thus anticipating the "second fragment of consisting of from 1 to 5 amino acid residues joined at least one of the N- or C-terminus of the first fragment, wherein the presence of the second fragment has no significant effect on the polypeptide". As stated before, the patent teaches at column 6 teach various formulation suitable for oral, topical, parenteral administration. For claim 31, the instant specification at page 15, 2nd paragraph says that immunomodulatory compound is a cytotoxic or cytostatic agent. Therefore the various antibodies and fragments at column 6 of the patent are considered as cytotoxic or cytostatic agent. Since the structure of

the prior art is same as the structure of the instantly claimed product, the product of the prior art inherently possesses the same

Claims 27, and 28 remain rejected, and claims **21 is newly rejected** under 35 U.S.C. 102(b) as being anticipated by Chin-Lee Wu et al., (May 1995, Molecular and Cellular Biology, vol. 15, pages 2536-2546).

Claims 27 and 28 are interpreted as drawn to a polypeptide comprising SEQ ID NOs 1-7 as the first portion, wherein said polypeptide further comprises a sequence of amino acids not naturally contiguous to the first portion in DP-1, wherein said polypeptide further comprises a transmembrane signal (claim 28).

As for claim 21, this rejection is made because "consisting of" in line 1 along with "or" in line 3 is interpreted as Markush group language, not transitional phrase to determine the scope of the claims. The transitional phrase is determined to be "corresponding" in line 1 of claim 21 step (i) and (ii) respectively, and the transitional phrase "corresponding" is broadly interpreted as opening transitional phrase, i.e. to include the unrecited sequence.

Applicant argues that applicant believes that Chin-Lee Wu et al., do not teach the instantly claimed invention.

This argument is considered fully but found unpersuasive. As stated in the previous Office actions, Chin-Lee Wu et al., teach a human DP-2 protein at page 2538. The protein of Chin-Lee et al., shown at Fig. 1A comprises instant SEQ ID NOs 1-7 as the first portion, wherein said polypeptide further comprises a sequence of amino acids (i.e., a human DP-2) not naturally contiguous to the first portion in DP-1.

As for claim 28 drawn to a membrane translocation sequence, the art does not teach where in the human DP-2 lies a nuclear transmembrane signal. However, Apostolova et al., J Biol Chem. 2002 Sep 13;277(37):34471-9, teach that the human DP-2 inherently has a nuclear membrane translocation sequence. Note the abstract. Thus, the protein of Chin-Lee et al., shown at Fig. 1A inherently comprises a membrane translocation sequence.

As for claim 21, the prior art of record teach a protein corresponding to residues 163 to 199 of DP-1, i.e. the entire full sequence of DP-1 comprising 163 to 199 of DP-1 (the instant SEQ ID NO: 1). Note Fig. 1 at page 2538.

Claim 25 **is newly rejected** under 35 U.S.C. 102(b) as being anticipated by Dynlacht et al., Proc Natl Acad Sci U S A. 1994 Jul 5;91(14):6359-63.

As stated above for rejection of claim 21, this rejection is made because "consisting of" in line 1 along with "or" in line 3 is interpreted as Markush group language, not transitional phrase to determine the scope of the claims. The transitional phrase is determined to be "corresponding" in line 1 of claim 21 step (i) and (ii) respectively, and the transitional phrase "corresponding" is broadly interpreted as opening transitional phrase, i.e. to include the unrecited sequence.

Dynlacht et al., teach Drosophila DP protein at Fig. 3, which is a variant of SEQ ID NO: 1 with total 5 amino acids substitutions in the SEQ ID NO: 1. Note the attached sequence alignment (Exhibit A). As for the function recited, since the structure is the same, the product of the prior art inherently possess the function. Further, since the

product of prior art interacts with a E2F protein (note Fig 5, and abstract), the product of the prior art appears to have the instantly recited function.

The Office does not have the facilities and resources to provide the factual evidence needed in order to establish that the protein of the prior art does not possess the functional characteristics of the instantly claimed variant. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed variant is different from the product taught by the prior art and to establish patentable differences. See In re Best 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

Claim Rejections - 35 USC § 112

Claim 36 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 36 recites "isolated product" comprising polypeptide and a cytostatic or cytotoxic agent.. However, Claims 30, and 31 with the same active ingredients as the instant claims recite "composition" the preamble. It is not clear whether "an isolated product" and "composition" has any difference in the scope. For example, the cytotoxic agent and polypeptide is a single molecule in the instant claim vs. two different molecules in the claims reciting "composition". The limitation "as a combined preparation" in claim 36 suggests that the claimed invention is "composition". Using the same terminology throughout the specification would be more clearer in terms of determining the scope of the invention, and less confusing.

For the purpose of this Office action, the scope of the invention is determined to be a composition comprising the polypeptide and a cytotoxic agent. However, this treatment does not relieve applicant the burden of responding to this rejection.

Conclusion

Claims 26, and 29 are objected because they depend on the rejected claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 571-272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey C Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MISOOK YU, Ph.D.
Examiner
Art Unit 1642

A;Title: Heterodimerization of the transcription factors E2F-1 and DP-1 leads to cooperd
A;Reference number: A48585; MUID:94010284
A;Accession: A48585
A;Status: preliminary; nucleic acid sequence not shown
A;Molecule type: mRNA
A;Residues: 1-410 <HEL>
A;Cross-references: GB:L23959; NID:g414316; PIDN:AAA58440.1; PID:g414317
C;Superfamily: transcription factor DP
C;Keywords: DNA binding; transcription factor

Query Match 100.0%; Score 186; DB 2; Length 410;
Best Local Similarity 100.0%; Pred. No. 5.3e-18;
Matches 37; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

Qy 1 KNIRRRVYDALNVLMAMNIISKEKKEIKWIGLPTNSA 37
||||||||||||||||||||||||||||||||||||||
Db 163 KNIRRRVYDALNVLMAMNIISKEKKEIKWIGLPTNSA 199

RESULT 3
T12511
hypothetical protein DKFZp434G222.1 - human (fragment)
N;Alternate names: E2F dimerization partner 2
C;Species: Homo sapiens (man)
C;Date: 23-Jul-1999 #sequence_revision 23-Jul-1999 #text_change 17-Nov-2000
C;Accession: T12511; A57381; I37297; I39180
R;Ansorge, W.; Wirkner, U.; Mewes, H.W.; Gassenhuber, J.; Wiemann, S.
submitted to the Protein Sequence Database, June 1999
A;Reference number: Z17527
A;Accession: T12511
A;Status: preliminary
A;Molecule type: mRNA
A;Residues: 1-416 <ANS>
A;Cross-references: EMBL:AL080206
A;Experimental source: adult testis; clone DKFZp434G222
R;Wu, C.L.; Zukerberg, L.R.; Ngwu, C.; Harlow, E.; Lees, J.A.
Mol. Cell. Biol. 15, 2536-2546, 1995
A;Title: In vivo association of E2F and DP family proteins.
A;Reference number: A57381; MUID:95257935
A;Accession: A57381
A;Status: preliminary
A;Molecule type: mRNA
A;Residues: 'M',33-416 <WUA>
A;Cross-references: GB:L40386; NID:g703084; PIDN:AAA69016.1; PID:g703085
R;Zhang, Y.; Chellappan, S.P.
Oncogene 10, 2085-2093, 1995
A;Title: Cloning and characterization of human DP2, a novel dimerization partner of E2F.
A;Reference number: I37297; MUID:95303470
A;Accession: I37297
A;Status: preliminary; translated from GB/EMBL/DDBJ
A;Molecule type: mRNA
A;Residues: 'M',33-143,'Q',144-416 <ZHA1>
A;Cross-references: EMBL:U18422; NID:g604478; PIDN:AAB60378.1; PID:g604479
A;Accession: I39180
A;Status: preliminary; translated from GB/EMBL/DDBJ
A;Molecule type: mRNA
A;Residues: 'M',33-49 <ZHA2>
A;Cross-references: EMBL:U35117; NID:g1008545; PIDN:AAC50642.1; PID:g1008546
C;Genetics:
A;Gene: GDB:TFDP2; DP2
A;Cross-references: GDB:638814
A;Map position: 3q23-3q23
A;Note: DKFZp434G222.1
C;Superfamily: transcription factor DP

Query Match 100.0%; Score 186; DB 2; Length 416;
Best Local Similarity 100.0%; Pred. No. 5.4e-18;
Matches 37; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

Qy 1 KNIRRRVYDALNVLMAMNIISKEKKEIKWIGLPTNSA 37
||||||||||||||||||||||||||||||||||||||
Db 148 KNIRRRVYDALNVLMAMNIISKEKKEIKWIGLPTNSA 184

RESULT 4
S30049
transcription factor DRTF1 chain 1 - mouse
N;Alternate names: transcription factor DP-1
C;Species: Mus musculus (house mouse)
C;Date: 30-Sep-1993 #sequence_revision 30-Sep-1993 #text_change 10-Dec-1999
C;Accession: S30049; S34572
R;Girling, R.; Partridge, J.F.; Bandara, L.R.; Burden, N.; Totty, N.F.; Hsuan, J.J.
Nature 362, 83-87, 1993
A;Title: A new component of the transcription factor DRTF1/E2F.
A;Reference number: S30049; MUID:93188967
A;Accession: S30049
A;Molecule type: mRNA
A;Residues: 1-429 <GIR1>
A;Cross-references: EMBL:X72310
A;Accession: S34572
A;Molecule type: protein
A;Residues: 75-90;131-151;164-184;191-207;235-249;281-293;302-313;321-328 <GIR2>
C;Superfamily: transcription factor DP
C;Keywords: DNA binding; transcription factor
F;84-204/Domain: DNA binding #status predicted <DNA>

Query Match 100.0%; Score 186; DB 2; Length 429;
Best Local Similarity 100.0%; Pred. No. 5.6e-18;
Matches 37; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

Qy 1 KNIRRRVYDALNVLMAMNIISKEKKEIKWIGLPTNSA 37
||||||||||||||||||||||||||||||||||||||
Db 163 KNIRRRVYDALNVLMAMNIISKEKKEIKWIGLPTNSA 199

RESULT 5
B55745
transcription factor DP - fruit fly (Drosophila melanogaster)
C;Species: Drosophila melanogaster
C;Date: 25-Aug-1995 #sequence_revision 25-Aug-1995 #text_change 10-Dec-1999
C;Accession: B55745
R;Dynlacht, B.D.; Brook, A.; Dembski, M.; Yenush, L.; Dyson, N.
Proc. Natl. Acad. Sci. U.S.A. 91, 6359-6363, 1994
A;Title: DNA-binding and trans-activation properties of Drosophila E2F and DP prote
A;Reference number: A55745; MUID:94294381
A;Accession: B55745
A;Status: preliminary; nucleic acid sequence not shown
A;Molecule type: mRNA
A;Residues: 1-377 <DYN>
A;Cross-references: GB:X79708; NID:g516866; PID:g516867
C;Genetics:
A;Gene: FlyBase:Dp
A;Cross-references: FlyBase:FBgn0011763
C;Superfamily: transcription factor DP

Query Match 89.2%; Score 166; DB 2; Length 377;
Best Local Similarity 86.1%; Pred. No. 2.9e-15;
Matches 31; Conservative 4; Mismatches 1; Indels 0; Gaps 0;

Qy 1 KNIRRRVYDALNVLMAMNIISKEKKEIKWIGLPTNS 36
|||||||||||||||:|:|||:||||:||||| ||
Db 145 KNIRRRVYDALNVLMAINVISKDKKEIRWIGLPANS 180

RESULT 6
T25207
hypothetical protein T23G7.1 - Caenorhabditis elegans
C;Species: Caenorhabditis elegans
C;Date: 15-Oct-1999 #sequence_revision 15-Oct-1999 #text_change 15-Oct-1999
C;Accession: T25207
R;Barlow, K.
submitted to the EMBL Data Library, December 1995